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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

**In re United States Patent Application of:**

**Applicant:** Jason C.H. SHIH

**Application No.:** 10/007,613

**Date Filed:** October 26, 2001

**Title:** METHOD AND  
COMPOSITION FOR  
STERILIZING  
SURGICAL  
INSTRUMENTS

**Docket No.:** 4171-102 CIP

**Examiner:** Zachariah LUCAS

**Art Group:** 1648

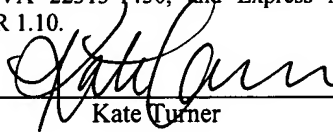
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Kate Turner

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**REPLY BRIEF FILED PURSUANT TO 37 CFR §1.193(b)(1)**  
**IN RESPONSE TO THE MARCH 22, 2005 EXAMINER'S ANSWER**  
**IN U.S. PATENT APPLICATION NO. 10/007,613**

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Sir:

This Reply Brief is filed under the provisions of 37 C.F.R. §1.193(b)(1), and responds to the Examiner's Answer dated March 22, 2005 in this appeal.

## **ISSUES ADDRESSED IN THIS REPLY BRIEF**

The following issue is addressed in this Reply Brief, in response to the Examiner's Answer:

### **Issue #2**

Whether appellant's claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82 are obvious over disclosure by the **WHO** reference ("WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation," World Health Organization (WHO), March 23-26, 1999), in view of the teachings of **Huth** (U.S. Patent No. 6,448,062), **Vlass** (U.S. Patent No. 6,210,639), **Potgeiter** (U.S. Statutory Invention Registration No. H001,818), **Bolton** ("Molecular Characteristics of the Major Scrapie Prion Protein," Biochemistry, Vol. 23, No. 25, pp. 5898-5906, December 1984), **Oesch** ("Properties of the Scrapie Prion Protein: Qualitative Analysis of Protease Resistance," Biochemistry, Vol. 33, No. 19, pp. 5926-5931, May 1994), and/or **Shih** (U.S. Patent No. 5,171,682).

This issue is addressed at below.

### **Issue #2: Patentability of Claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82 Over the Cited References – Claim 39 is Representative**

Claim 39, which is representative of claims 40-51, 53-56, 63, 71, 73, 74, 80, and 82, expressly requires:

"A system comprising:

- (a) one or more articles susceptible to contamination by infectious prion protein;
- (b) means for heating said articles;
- (c) a proteolytic enzyme selected from the group consisting of keratinases and subtilisins; and
- (d) means for exposing said articles to said proteolytic enzyme,

wherein said one or more articles are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration, wherein said articles are characterized by a second elevated temperature in a range of from

**about 50°C to about 65°C and exposure to said proteolytic enzyme during a second, subsequent duration.”**

The language of claim 39 **expressly requires** that the prion-contaminated articles be characterized by “**a first elevated temperature of at least 40°C and not more than about 150°C during a first duration**” and “**a second elevated temperature in a range of from about 50°C to about 65°C and exposure to said proteolytic enzyme during a second, subsequent duration.**” Further, such express requirement in claim 39 imposes **an implicit structural limitation** on the claimed system of claim 39, i.e., such system must provide **a specific arrangement of the recited elements, i.e., the articles, the heating means, the proteolytic enzyme, and the exposing means,** to enable the prion-contaminated articles to be **characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration and a second elevated temperature in a range of from about 50°C to about 65°C and exposure to the proteolytic enzyme during a second, subsequent duration.**

**The cited references, either taken singularly or in combination, do not provide any derivative basis for prion-contaminated articles that are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration and a second elevated temperature in a range of from about 50°C to about 65°C and exposure to the proteolytic enzyme during a second, subsequent duration, as expressly required by claim 39. Further, nothing in the cited references implicitly provides for arrangement of articles, heating means, proteolytic enzyme, and exposing means to allow such articles to be so characterized.**

The hypothetical combination of multiple references, i.e., the WHO reference and the Huth, Vlass, Potgeiter, Bolton, and Oesch references as suggested by the Examiner only yields **a system that contains a mere aggregate of** articles, heating means, proteolytic enzyme and exposing means, but **such system does not provide for any specific arrangement of elements** that enables the prion-contaminated articles to be characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration and a second elevated temperature in a range of from about 50°C to about 65°C and exposure to the proteolytic enzyme during a second, subsequent duration, as expressly required by claim 39 of the present application. In fact, none of the secondary references acknowledges, or even recognizes, the advantages of arranging the articles, the heating means, the proteolytic enzyme and the exposing means to allow the articles to be characterized by an elevated temperature in a range of from about 50°C to about 65°C during exposure to a proteolytic enzyme.

In the March 22, 2005 Examiner's Answer, the Examiner asserted that the combination of multiple references contains all of the structural elements of the claimed system of claim 39, and that the functional limitations recited by claim 39 regarding the heating of the articles to be treated to different temperatures at different time points describe method steps and are not sufficient to distinguish the claimed system of claim 39 from the system yielded by the hypothetical combination of the multiple references so long as such system yielded by prior art combination would be capable of performing the method steps described by such functional limitation.

Appellant respectfully disagrees with the Examiner's assertions, based on the holdings by the U.S. Court of Appeals in the Federal Circuit in *In re Mills*, 16 USPQ2d 1430 (CAFC 1990), which are applicable to the present case.

The claimed invention in *In re Mills* required:

“Apparatus for producing an aerated cementitious composition, comprising:  
a mixing chamber being open to atmosphere and containing mixing means,  
feed means for feeding ingredients comprising cement, foaming agent and liquid to the mixing chamber,  
mixing means for mixing ingredients fed to the mixing chamber, pump means for pumping the mixed ingredients to a desired site and having a pump inlet connected to an outlet of the mixing chamber,  
drive motor means connected through gearbox means providing a pumping capacity of the pump means greater than the feed rate of the ingredients to the mixing chamber provided by the feed means, such that in operation air is drawn into the mixing chamber, and entrained in the mixed ingredients.”

The Office found such claimed invention obvious under 35 U.S.C. §103 over a single reference Mathis, which discloses all the structural elements recited in the claimed invention. Specifically, the Office found “correspondence in the Mathis reference for all of the subject matter recited in appellants' claims” and asserted that that the claimed invention involves an apparatus, instead of a method, that “[i]n our opinion, the differences between claim 6 and the Mathis machine... lie solely in the functional language of the claim,” and that “the Mathis machine is capable of being operated in such a fashion as to cause [the output] pump 18 to draw air into the mixing chamber 17 so that it is entrained in the mixture.”

In reviewing the Office's position, the Federal Circuit Court drew a distinction between the lack of novelty rejection under 35 U.S.C. §102 and the obviousness rejection under 35 U.S.C. §103, by stating that:

*"The Board found that the difference between the claimed subject matter and the prior art resided solely in functional language and that appellant had to show that the prior art device lacked the functional characteristics of the claimed device, citing In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Ludtke, however, dealt with a rejection for lack of novelty, in which case it was proper to require that a prior art reference cited as anticipating a claimed invention be shown to lack the characteristics of the claimed invention. That proof would in fact negate the assertion that the claimed invention was described in the prior art. We are here, however, facing an obviousness issue. It is not pertinent whether the prior art device possesses the functional characteristics of the claimed invention if the reference does not describe or suggest its structure. That is the case here..." (see In re Mills at 1432)*

The Court found that the Mathis reference contains no suggestion of "pump means and the feed means providing a pumping capacity of the pump means greater than the feed rate of ingredients to the mixing chamber provided by the feed means, such that in operation air is drawn into the mixing chamber, and air entrained in the mixed ingredients," as required by the claimed invention, and that "the claimed apparatus is different from that of Mathis, since the fact that motor 6 of Mathis (the feed means) can be run at a variable speed does not require that motor 20 (connected to the pump) be run at a lesser speed 'such that in operation air is drawn into the mixing chamber and air entrained in the mixed ingredients.'"

Most importantly, the Court expressly stated that:

**"While Mathis' apparatus may be capable of being modified to run the way Mills' apparatus is claimed, there must be a suggestion or motivation in the reference to do so."**

The holdings by the Court in *In re Mills* are applicable to the facts of the present case.

First, none of the references cited by the Examiner teaches or suggests all the structural elements of claim 39 of the present application. Instead, the Examiner had to combine: (1) the teachings by the WHO

reference about sterilization of medical devices susceptible to prion contamination, by treating the medical devices with heat and then with routine sterilization process; (2) the teachings by the **Huth, Vlass, and Potgeiter** references about use of various enzymes, including keratinases, for disinfecting medical instruments; and (3) the teachings by the **Bolton and Oesch** references about heat denaturation of the prion proteins to increase susceptibility of the prion proteins to enzymatic degradation, and asserted that appellant's claimed invention is obvious over the combination of teachings by the **WHO** reference and **Huth, Vlass, Potgeiter, Bolton, and Oesch**, in yielding all the structural elements of the claimed system.

Therefore, it is clear that the present case involves an obviousness issue under 35 U.S.C. §103, as dealt by the Court in *In re Mills*, NOT a lack of novelty issue under 35 U.S.C. §102.

In this case, the hypothetical combination of the multiple references as suggested by the Examiner contains NO suggestion for arranging the prion-contaminated articles, the heating elements, the proteolytic enzyme, and the exposing means to allow the articles to be characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration and a second elevated temperature in a range of from about 50°C to about 65°C during exposure to a proteolytic enzyme at a second, subsequent duration, as expressly required by claim 39.

**The system claimed by claim 39 of the present application is different from the system yielded by the hypothetical combination of the multiple references suggested by the Examiner,** since the fact that the heating means disclosed by the WHO reference and the Bolton reference can be set to different temperatures does not require such heating means be set in a manner for maintaining the prion-contaminated articles at a first elevated temperature of at least 40°C and not more than about 150°C during a first duration and a second elevated temperature in a range of from about 50°C to about 65°C during exposure to a proteolytic enzyme during a second, subsequent duration.

Further, although the system yield by the hypothetical combination of the multiple references may be capable of being modified to run the way appellant's system is claimed, as the Examiner argued in the March 23, 2004 Examiner's Answer (see page 8, first full paragraph of the Examiner's Answer), **there must be a suggestion or motivation in the cited references to do so,** according to the Court's holding in *In re Mills*.

Unfortunately, **none of the cited references provides the suggestion or motivation** for running a system

that contains prion-contaminated articles, heating means, proteolytic enzyme, and exposing means in such a manner that the prion-contaminated articles are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration and a second elevated temperature in a range of from about 50°C to about 65°C and exposure to the proteolytic enzyme during a second, subsequent duration, as expressly required by claim 39.

**Therefore, the cited references fail to describe or suggest Appellant's claimed system as recited by claim 39, and claim 39 of the present application patentably distinguishes over such cited references.**

In the March 22, 2005 Examiner's Answers, the Examiner asserted that "there is no requirement that the enzymes be introduced to the articles during the heating process," that "there is also no inherent requirement that the heating device and the means for exposing the articles to the enzymes having any specific positional relationship," and that "the claims therefore present no requirements on the arrangement of the various parts of the claimed system other than their presence."

Appellant respectfully disagrees with such assertions by the Examiner.

Claim 39 requires that the prion-contaminated articles be characterized by a second elevated temperature in a range of from about 50°C to about 65°C and exposure to the proteolytic enzyme during a second, subsequent duration. The second elevated temperature of from about 50°C to about 65°C is significantly higher than room temperature (about 23°C), which indicates that the prion-contaminated articles is either simultaneously heated during enzyme exposure, or that the point of enzyme exposure is sufficiently close to the point of heating so that the heated articles maintain an elevated temperature of from about 50°C to about 65°C during the enzyme exposure without additional heating.

Either situation requires that the heating device and the means for exposing the articles to the enzymes be sufficiently close to each other to allow either simultaneous heating and enzyme exposure, or maintenance of elevated temperature during enzyme exposure without additional heating. If the heating device and the means for enzyme exposure were too far from each other, the heated articles would have cooled down to room temperature before enzyme exposure and would not be characterized by a second elevated temperature in a range of from about 50°C to about 65°C and exposure to the proteolytic enzyme during a second, subsequent duration.

**Therefore, the Examiner's assertion that the claims of the present application present no requirements on the arrangement of the various parts of the claimed system other than their**

**presence is incorrect.**

It therefore is respectfully requested that the Board take cognizance of the absence of any proper basis of the §103 rejection of claim 39, as representative of appealed claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82, and correspondingly reverse the Examiner's rejection of such claims.

### **CONCLUSION**

Based on all of the foregoing, the Board of Patent Appeals and Interferences is requested to reverse the decision of the Examiner finally rejecting claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82.

This Reply Brief is submitted in triplicate.

If any fee or charge is required for entry of this Reply Brief, authorization hereby is given to charge same to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,



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Yongzhi Yang  
Reg. No. 56,310  
Attorney for Appellants

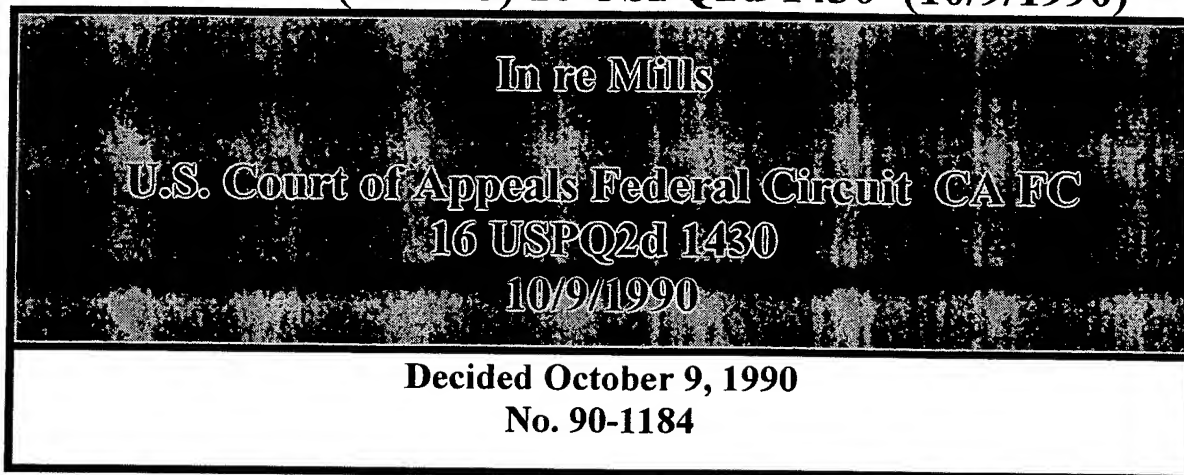
INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW  
P.O. Box 14329  
Research Triangle Park, NC 27709  
Telephone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File: 4171-102 CIP





**FULL TEXT OF CASES (USPQ2D)**  
All Other Cases

**In re Mills (CA FC) 16 USPQ2d 1430 (10/9/1990)**



**Headnotes**

**PATENTS**

**1. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)**

Apparatus which produces aerated cementitious composition by driving output pump for its mixing chamber at capacity greater than feed rate of ingredients into mixing chamber, and thereby drawing air into composition, is not obvious in view of prior patent for mixing apparatus, even though device of prior patent provides for regulation of flow rate into mixing chamber, since patent contains no suggestion or motivation for overdriving output pump so as to entrain air in mixed ingredients.

**2. Patentability/Validity - Anticipation - In general (§ 115.0701)**

**Patentability/Validity - Obviousness - Relevant prior art - In general**

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**(§ 115.0903.01)**

Board of Patent Appeals and Interferences erred by requiring applicant to show that prior art reference lacked functional characteristics of claimed device, since even though such requirement would be proper for rejection based on lack of novelty, it is not pertinent whether prior art device possesses claimed invention's functional characteristics if, as here, application was rejected on basis of obviousness and reference does not describe or suggest claimed invention's structure.

**Case History and Disposition:**

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**Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.**

**Patent application of Peter S. Mills, serial no. 891,374, continuation of serial no. 607-805, filed May 4, 1984. From decision upholding examiner's rejection of claims 6-9 and 11-14, applicant appeals. Reversed.**

**Attorneys:**

**James C. Wray, McLean, Va, for appellant.**

**Muriel E. Crawford, assistant solicitor (Fred E. McKelvey, solicitor, with her on brief), for appellee.**

**Judge:**

**Before Miller, senior circuit judge, and Mayer and Lourie, circuit judges.**

**Opinion Text****Opinion By:**

**Lourie, J.**

This appeal is from the November 2, 1989, decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences (Board), Appeal No. 88-0141, affirming the examiner's rejection, under 35 U.S.C. §103, of claims 6-9 and 11-14 in Mills' application Serial No. 891,374, a continuation of Serial No. 607-805, filed May

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4, 1984, entitled "Methods of and Apparatus for Producing Aerated Cementitious Compounds." The remainder of the claims (1-5, 10, and 15) have all been cancelled. We reverse.

# I

## BACKGROUND

### A. *The Invention*

Mills' claimed invention is an apparatus for producing aerated cementitious compositions. Claim 6 is the broadest claim:

6. Apparatus for producing an aerated cementitious composition, comprising a mixing chamber being open to atmosphere and containing mixing means, feed means for feeding ingredients comprising cement, foaming agent and liquid to the mixing chamber, mixing means for mixing ingredients fed to the mixing chamber, pump means for pumping the mixed ingredients to a desired site and having a pump inlet connected to an outlet of the mixing chamber, drive motor means connected through gearbox means providing a pumping capacity of the pump means greater than the feed rate of the ingredients to the mixing chamber provided by the feed means, such that in operation air is drawn into the mixing chamber, and entrained in the mixed ingredients.

The essence of Mills' invention is the machine's ability to aerate a cementitious composition by driving the output pump at a capacity greater than the feed rate, thereby drawing air into the composition. This aeration produces a composition with substantially lower density than standard cementitious composition mixing ingredients.

### B. *The Reference*

The sole reference upon which the Board relied in affirming the examiner's rejection was Mathis et al. U.S. Patent 4,117,547 (Mathis). 1 Mathis discloses a mixing chamber which is open to the atmosphere and which contains a mixing means. Two feed means for feeding ingredients in the mixing chamber are provided. The first feed means may consist of a screw conveyer and the second, a flow metering device such as an adjustable valve. A pump means pumps the mixture from the mixing chamber to a desired site and a drive motor means is connected to mixing means and pump means. A separate motor drives the feed means.

A control system exists to arrest the feed means so as not to overfill the mixing chamber. This system comprises a level detector in the mixing chamber, which signals the feed means to close when the mixing chamber stores the predetermined maximum permissible quantity of material.

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### C. *The Rejection*

The Board affirmed the examiner's Section 103 rejection of claims 6-9 and 11-14,

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"finding correspondence in the Mathis reference for all of the subject matter recited in the appellants' claims. ..." With regard to Mills' claim language relating to aerating the mixture, the Board stated: "[i]n our opinion, the differences between claim 6 and the Mathis machine ... lie solely in the functional language of the claim." The Board further found that Mathis teaches the use of separate input and output motors in order to permit the various mixing means and pumps to operate at different rates, and that Mathis "contemplates a situation wherein the rate of the outlet pump would be greater than the inlet pumps...." The Board concluded on this point: "[w]e are of the opinion that the Mathis machine is capable of being operated in such a fashion as to cause [the output] pump 18 to draw air into the mixing chamber 17 so that it is entrained in the mixture." The Board also agreed with Mills' contention that Mathis is not directed to the problem of producing aerated cementitious material, but noted that Mills is not claiming a method, but an apparatus, and all of Mills' apparatus structure is present in the Mathis machine.

## II

### DISCUSSION

All of the rejected claims are apparatus claims. The Board found "correspondence in the Mathis reference for all of the subject matter recited in appellants' claims" and that "[t]he Mathis machine discloses all of the structure set forth in claim 1" (a method claim not before us). It asserts that the use of such a mechanism would have been obvious and that the differences between claim 6 and the Mathis machine lie solely in the functional language of the claim, the preamble merely stating an intended use for the machine. This language suggests a lack of novelty rejection under 35 U.S.C. §102, rather than an obviousness rejection. However, no Section 102 rejection has been made or is before us. What is before us is a rejection for obviousness, and we must decide whether the Board erred in that rejection.

We note first that nonobviousness is a question of law to be determined from the facts. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). We review the Board's determination of obviousness, based on the scope and content of the Mathis reference and the differences between the Mathis reference and the Mills claims, for correctness or error. *In re Carleton*, 599 F.2d 1021 1024 n.14, 202 USPQ 165, 169 n.14 (CCPA 1979).

[1] After reviewing the record, the arguments in the briefs, and the Mathis reference, we conclude that Mathis would not have rendered the claimed invention obvious. The closest Mathis comes to suggesting Mills' claimed apparatus is at column 3, lines 42-47, which states

he rate at which the inlet 2b receives a solid constituent depends on the speed of the feed screw 4. Such speed can be regulated by a prime mover 6 which includes a variable-speed transmission.

This brief reference contains no suggestion of "pump means and the feed means providing a pumping capacity of the pump means greater than the feed rate of ingredients to the mixing chamber provided by the feed means, such that in operation air is drawn into the mixing chamber, and air entrained in the mixed ingredients," as provided for in Mills' claim 6. While Mathis' apparatus may be capable of being modified to run the way Mills' apparatus is claimed, there must be a suggestion or motivation in the reference to

do so. *See In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification."). We see no such suggestion. The apparatus claimed by Mills is different from that of Mathis, since the fact that motor 6 of Mathis (the feed means) can be run at a variable speed does not require that motor 20 (connected to the pump) be run at a lesser speed "such that in operation air is drawn into the mixing chamber and air entrained in the mixed ingredients."

[2] The Board found that the difference between the claimed subject matter and the prior art resided solely in functional language and that appellant had to show that the prior art device lacked the functional characteristics of the claimed device, citing *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). *Ludtke*, however, dealt with a rejection for lack of novelty, in which case it was proper to require that a prior art reference cited as anticipating a claimed invention be shown to lack the characteristics of the claimed invention. That proof would in fact negate the assertion that the claimed invention was described in the prior art. We are here, however, facing an obvious

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ness issue. It is not pertinent whether the prior art device possesses the functional characteristics of the claimed invention if the reference does not describe or suggest its structure. That is the case here. Given the facts before us, we hold that the Board was in error in affirming the examiner's rejection of claims 6-9 and 11-13 as obvious in view of Mathis, and we therefore *reverse* the Board.  
REVERSED

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#### Footnotes

Footnote 1. The examiner rejected the claims at issue under 35 U.S.C. §103 as being unpatentable not only over Mathis but also in view of Gibson et al. U.S. Patent 2,717,770. However, the Board affirmed the examiner's rejection of claims 6-9 and 11-14 based solely on the Mathis reference. With regard to Gibson the Board stated: We view the teachings of Gibson at best as being merely confirmatory of the fact that aerated mixtures can be produced by machines in which a pump means operates upon a mixing chamber at a greater rate than the ingredients are fed thereunto so that air is drawn into the mixing chamber and entrained in the mixed ingredients.  
App. 2.

- End of Case -  
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